





**ETYMOTIC RESEARCH, INC.**

513(f) Reclassification Petition – TV-TIP Sound Amplifier

## **SECTION F - BASIS FOR DISAGREEMENT WITH CLASSIFICATION**

Etymotic Research Inc. believes that the TV-TIP Sound Amplifier should not be class III by operation of section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) under the criteria in Sec. 860.3(c) due to the fact that it is much like an air-conduction hearing aid (21 CFR 874.3300). Air-conduction hearing aids have a history of being safe and effective and are classified as class I exempt. General controls are sufficient to provide reasonable assurance of the safety and effectiveness of this device. This device is intended for the general population and does not present a potential unreasonable risk of illness or injury.